

# Office Action Summary

Application No.

09/521,367

Applicant(s)

KARASAWA, HITOSHI

Examiner

Paul A Roberts

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 11 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 7/11/02 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## **DETAILED ACTION**

### ***Priority***

1. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Japan on 3/12/99. It is noted, however, that applicant has not filed a certified copy of the Japanese application as required by 35 U.S.C. 119(b).

### ***Drawings***

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore:

- a. The 'opening/closing valve' in claims 4 and 6
- b. The 'hole diameter changeable member' in claim 18
- c. The 'second sealing portion' in claim 4
- d. The 'housing' in claim 19
- e. The 'port for introducing a surgical instrument' in claim 19

must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### ***Specification***

Applicant is reminded of the proper language and format for an abstract of the disclosure.

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The abstract should be in **narrative form** and generally limited to a single paragraph on a separate sheet within the range of **50 to 150** words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and **legal phraseology** often used in patent claims, such as "means" and "said," should **be avoided**. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

3. The abstract is objected to because it is over 150 words and uses technical legal phraseology.

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

4. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

- f. The 'opening/closing valve' in claim 2 is not described.
- g. On page 22 line 13-15 the specification described a 'first' and 'third' 'sealing portion' without describing a 'second sealing portion.' Since claim 5 refers to a second portion, the second member should be described.
- h. The 'hole diameter changeable member' in claim 18 is not described.
- i. The 'housing' in claim 19 is not described
- j. The 'port for introducing a surgical instrument' in claim 19 is not described

5. The disclosure is objected to because of the following informalities:

- k. On page 39, line 23 the overhung should be deleted.

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1. One page 39, line 25 the second 'the' should be deleted.

Appropriate correction is required.

### *Claim Objections*

2. Claim 1,18 is objected to because the malapropian use of the word 'adopted.' The word 'adapted' is suggested (page 48, line 22.)

With regard to claim 18 the word 'hold' should be 'hole' (page 51, lines 13, & 15)

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 4-6,15,20,23 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claim 4, 5, 6 recites the limitation "the opening/closing valve" in line 6, line 9, line 13, & line 16. There is insufficient antecedent basis for this limitation in the claim.

4. Claim 11 is rejected because the recitation that "the sealing member is deformed by pushing force using the fixing member" is indefinite, in that it is merely functional language not supported by recitation in the claim of sufficient structure to warrant the presence of the functional language.

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5. Claim 15 is objected to because an object cannot be 180 degrees and over 180 degrees distant from another object at the same time. The word 'or' as opposed to 'and' should be used if the alternative form is desired.
6. Claim 20 recites the limitation "the housing" in line 5. There is insufficient antecedent basis for this limitation in the claim.
7. Claim 23 is objected to because the shoulder portion is directed connected to the unspecified sealing means. It cannot be in the vicinity of the periphery, since it is directly connected to the periphery of the sealing means.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claim 1-5,8,10,15,16,18, 19, 20, & 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Kramer et al 5,792,113. Kramer teaches that a trocar can be assembled with:

- An insert portion capable of allowing a medical instrument to pass through it
- A holding portion equipped with an opening
- A removably mounted sealing member mounted to the holding portion
- A fixing member removably mounted to the sealing member

Please see the attached page figure 1. All of these parts are clearly labeled. The figure was taken from figure 1 in Kramer's patent 5,792,113.

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9. Regarding claim 2, Kramer teaches in lines 10-35 in column 1 that the valve in the holding portion can be opened and closed.

10. Regarding claim 3, Kramer clearly illustrates in Figure 2 that the fixing member is turnably mounted onto the holding portion (figure 2, items 17, 10, & 16.)

11. With respect to claim 4, Kramer clearly illustrates two sealing portions in the drawing in figure 2, where one of the sealing portions abuts against the valve that closes the holding portion.

12. Regarding claim 5, Kramer teaches that a flapper valve has a flexible lip, which swings out of the way of the instrument pushing on it. When the lip is in one position, it makes a seal with the sealing portion, and when it is in its second position there is a space between the sealing lip and the sealing portion.

13. Regarding claim 8, Kramer teaches that the sealing portion have an opening/hole to provide a pathway for a medical instrument to pass through the holding portion (lines 50-54, column 2.)

14. Regarding claim 15, Kramer illustrates that the fixing member has a hole that would serve to restrict the angle in which the medical instrument can be inserted or tilted (figure 4, item 17.)

15. Regarding claim 10, Kramer illustrates that the shoulder portion of his trocar forms a mesh at the sight of the sealing member. (Please see attached figure 2 taken from Kramer's patent figure 2.)

16. Regarding claim 16, Kramer illustrates that the sealing member is located between/ sandwiched between the fixing member and holding member. (See figure 2. Items 10,16, and 17).

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17. Regarding claim 17, Kramer teaches the sealing member (illustrated on the attached figure 2) also functions as the valve that opens and closes when an instrument is placed into or out of the passage.

18. With respect to claim 19, Kramer teaches that a trocar has:

- A housing with a space (column 2 line, 43-44)
- A port/passage for a surgical instrument (column 2, lines 64-65)
- A sealing means for closing the port (column 1, lines 30-33)
- A fixing member for fixing the sealing means. (see attached figure 1)
- A removably mountable sealing means (see attached figure 2, items 10, 16, 17)

19. Regarding claim 20, Kramer teaches that the seal used in the housing, for the purpose of ensuring air-tightness, is a flapper valve. A flap/flapper valve is by definition elastic in nature. Furthermore, a flexible lip portion is integral to a flapper valve and therefore indigenous to valve.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

20. Claims 6, 12-14, 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kramer as in view of Akui et al, 4,715,360. Kramer teaches that a sealing member is mounted to proximal end of the holding section, but fails to teach the existence of another sealing portion exists, and that it should have space between the first sealing portion. Akui teaches that another sealing

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portion should be used to seal the space between the medical instrument and the holding portion. This adaptation allows a greater range of medical instrument sizes to be used in the trocar, because a smaller hole member can be placed in the place of the larger one by placing it abut to the sealing member. It would have been obvious to one of ordinary skill in the art at the time of the invention to place the Akiu's endoscope forceps stopcock onto the proximal end of the holding portion of the Kramer device to allow a greater range instrument size.

21. Regarding claims 6, 13, and 14 Akui teaches that the arm portion, which is made of elastic material, should be oriented in the longitudinal axial direction w/ respect to the insert portion when the sealing member is mounted to the holding portion (see figure 2, items 30, 34, 52, 53, 54, 56, 50.) Since the material is elastic, it will be biased to return to the position with the lowest potential energy, which is the open position/1<sup>st</sup> position. This is at an angle of 180<sup>0</sup> or over (column 3, line 20.)

22. Claims 7,9,11, 21, & 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Kramer in view of Akiu as applied to claim 1 and 19 above, and further in view of Bencini, 5,401,248. The modified Kramer device uses a 'universal seal' as described on line 53-70. Kramer fails to teach that a different type of seal (a duck-billed valve or a slit valve) can be used. Bencini teaches that many different seals can be used to seal the passage of a trocar. Specifically, on line 69, column 1, Bencini mentions that a duck-billed valve can be applied to the trocar device. Furthermore, on line 3, column 2, Bencini mentions that a single slit design can be used as well. It would have been obvious to one of ordinary skill in the art at the time of the invention to select a slit valve or duck-billed valve to seal the trocar, since it has been held to be



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within the general skill of a worker in the art to select a well known valve on the basis of suitability for the intended use as a matter of obvious design choice.

23. In regard to claim 7, Akiu teaches that the sealing member has two sealing portions, where the first sealing portion is distanced from the second sealing portion. Furthermore, he illustrates that the 2<sup>nd</sup> sealing portion seals the space between the medical instrument and the holding portion (please refer to figure 2.)

24. Regarding claim 11, the sealing member as described by Akui in his abstract is deformed when the fixing object is inserted into the sealing member.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 5693031 A	Ryan et al.	Trocar with similar design to the applicant's
US 6106519 A	Long, Gary L. et al.	Holding portion and insert portion
US 5607397 A	Stephens at al.	Adaptor Cap and Trocar Assembly
US 5776112 A	Stephens, Randy R. et al.	Trocar matching applicant's design
US 5300036 A	Mueller, Richard L. et al.	Trocar with multiple converters

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A Roberts whose telephone number is (703) 305-7558. The examiner can normally be reached on 7:30-3:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Paul Roberts  
July 15, 2002

**MICHAEL J. MILANO  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700**

Figure 1

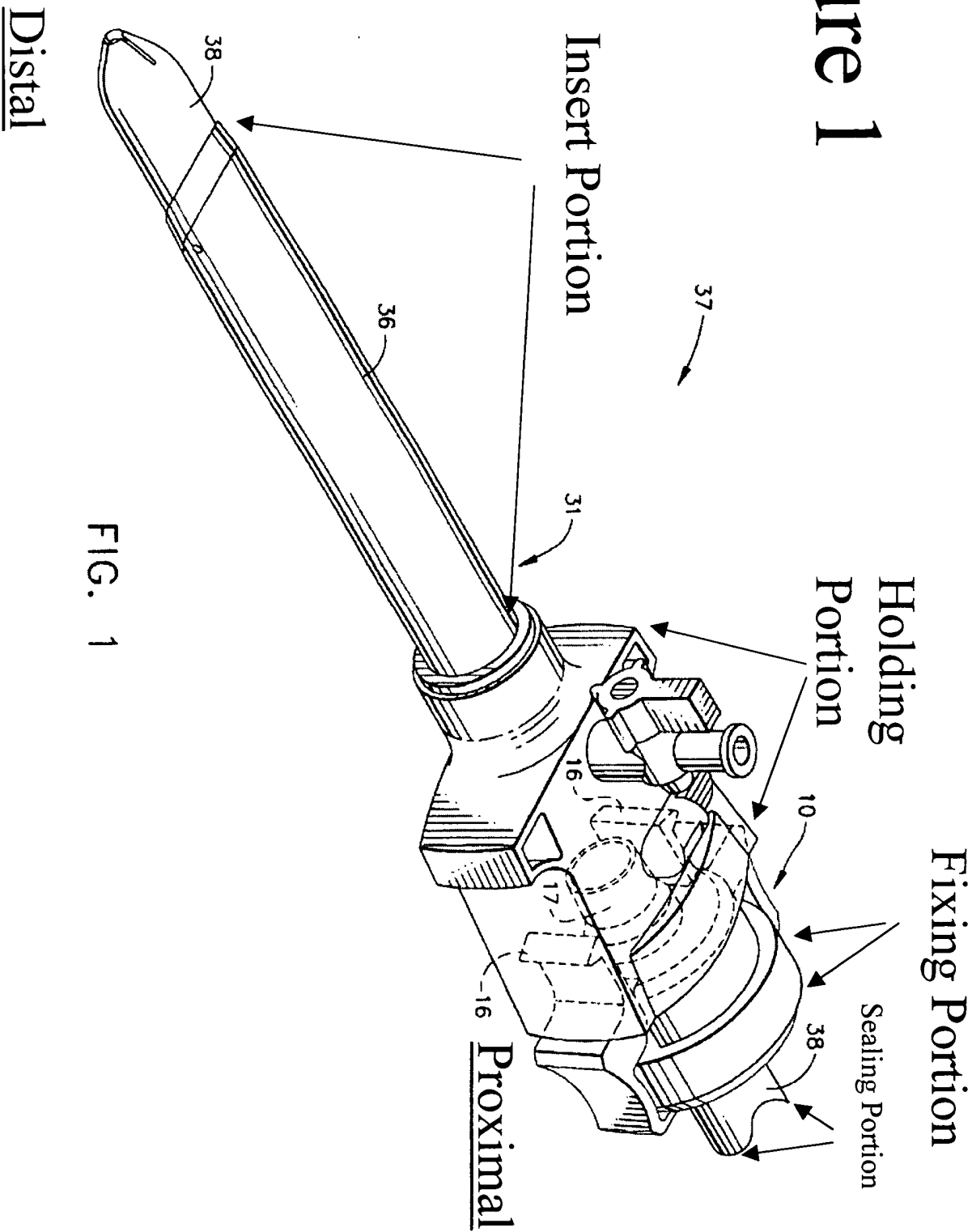


FIG. 1

# Figure 2

